

GERALD SINGLETON (208783)
gsingleton@singletoschreiber.com
 MIKAL C. WATTS (PRO HAC FORTHCOMING)
mcwatts@wattsguerra.com
 ALICIA D. O'NEILL (PRO HAC FORTHCOMING)
aoneill@wattsguerra.com
 ATTORNEYS FOR PLAINTIFFS

**UNITED STATES DISTRICT COURT
 CENTRAL DISTRICT OF CALIFORNIA**

**FARRAN ELDER, INDIVIDUALLY AND AS
 GUARDIAN AD LITEM OF N.E.S., MINOR**

Plaintiff(s),

v.

WALMART, INC.

Defendant.

Civil Action No.:

COMPLAINT & JURY DEMAND

DEMAND FOR JURY TRIAL

PLAINTIFFS' ORIGINAL COMPLAINT AND JURY DEMAND

Plaintiff Farran Elder, individually and as representative of N.E.S., a minor, pursuant to Fed. R. Civ. P. 17(c)(1)(A), by and through their undersigned counsel, bring this Complaint for damages against Defendant Walmart, Inc. (hereinafter, "Defendant") and in support, state the following:

1. This is an action brought on behalf of Plaintiffs, Farran Elder (hereinafter, "Plaintiff Mother"), the natural and general guardian and mother of N.E.S., (hereinafter, "Plaintiff Child"), a minor, arising out of the failure of Defendant to warn about the dangers of prenatal exposure to Paracetamol, also known as Acetaminophen (hereinafter "APAP"). As a result, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

2. Defendant entirely failed its duty to adequately warn of the hazards of prenatal exposure to APAP, which was a direct and proximate cause of Plaintiffs' injuries and associated

1 damages.

2 **STATEMENT OF PARTIES**

3 3. At all material times Plaintiffs have been citizens and residents of Los Angeles
4 County, California.

5 4. Walmart, Inc. is incorporated in Delaware with its principal place of business in
6 Bentonville, Arkansas.

7 5. Walmart, Inc. is involved in the research, development, testing, manufacture,
8 labeling, production, marketing, promotion, and/or sale of APAP through its over-the-counter
9 store brand, Equate (hereinafter, the “APAP Products”).

10 6. Walmart, Inc. is individually, and jointly and severally liable to Plaintiffs for
11 damages they suffered, arising from Each Defendant’s design, manufacture, marketing,
12 labeling, distribution, sale, and placement of the defective APAP Products into the market,
13 effectuated directly and indirectly through its agents, servants, employees, and/or owners, all
14 acting within the course and scope of its agencies, services, employments, and/or ownership.

15 7. Walmart, Inc. is vicariously liable for the acts and/or omissions of its employees
16 and/or agents, who were at all material times acting on behalf of Walmart, Inc. and within the
17 scope of its employment or agency.

18 **JURISDICTION and VENUE**

19 8. This Court has subject-matter jurisdiction under 28 U.S.C. § 1332(a), based on
20 complete diversity of citizenship between Plaintiffs and Defendant. *See supra* ¶¶ 3–4.

21 9. The amount in controversy exceeds \$75,000.

22 10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the events or
23 omissions giving rise to Plaintiffs’ claims occurred in this judicial district.

24 11. Defendant has conducted and continues to conduct substantial business in the
25 State of California and in this District, distribute the APAP Products in this District, receive
26 substantial compensation and profits from sales of the APAP Products in this District, and have
27 made material omissions and misrepresentations and breaches of warranties in this District and
28 caused injuries in this District to Plaintiffs, among others, so as to subject Defendant to in

1 personam jurisdiction in this District. It was foreseeable at all times that Defendant could be
 2 haled into court in the State of California for its conduct that caused injuries to citizens of
 3 California, like Plaintiffs in this action. An exercise of in personam jurisdiction by this Court
 4 over Defendant comports fully with due process and does not offend traditional notions of fair
 5 play and substantial justice.

6 12. Defendant is registered to transact business in California.

7 **FACTS COMMON TO ALL COUNTS**

8 **APAP Is Marketed as the Safe Pain Reliever for Pregnant Women, but APAP Can Cause**
 9 **ASD/ADHD in Children**

10 13. APAP is widely used by pregnant women to relieve pain or discomfort during
 11 the term of their pregnancy.

12 14. APAP was initially discovered in the late 1800's.

13 15. APAP was introduced to the US market in 1955 as the first aspirin-free pain
 14 reliever. APAP was originally marketed and sold as a product to reduce fever in children,
 15 packaged like a red fire truck with the slogan, "for little hotheads."

16 16. Billions of units of APAP are sold annually in North America alone.

17 17. APAP has long been marketed as the safest, and the *only* appropriate, over-the-
 18 counter pain relief drug on the market for pregnant women.

19 18. Forty to 65% of pregnant women in the United States use APAP during
 20 pregnancy.

21 19. Based upon information and belief, a majority of women who use APAP during
 22 pregnancy do so electively for the treatment of headaches, muscle pain, back pain, and
 23 discomfort.

24 20. These pregnant women electively choose to take APAP because Defendant has
 25 marketed APAP as a safe pain reliever for pregnant women.

26 21. However, scientific and epidemiological research shows that prenatal exposure
 27 to APAP alters fetal development significantly increasing the risks of neurodevelopmental
 28 disorders, including but not limited to, autism spectrum disorder ("ASD") and attention-

1 deficit/hyperactivity disorder (“ADHD”).

2 22. Undisturbed development of the human brain in utero is vital to the health and
3 wellness of a child’s development. The human brain is vulnerable and extremely sensitive in
4 utero. During this sensitive time-period in utero, certain chemicals have been found to cause
5 permanent brain injury at low exposure levels.

6 23. Once ingested by the mother, APAP is known to readily cross the placenta and
7 blood-brain barrier.

8 24. ASD is a serious neurological and developmental disorder that affects how
9 people interact with others, communicate, learn, and behave.

10 25. There are three functional levels of ASD, with Level 1 requiring support with
11 activities of daily living, Level 2 requiring substantial support with activities of daily living, and
12 Level 3 requiring very substantial support with activities of daily living.

13 26. Treatments for ASD include behavioral management therapy, cognitive behavior
14 therapy, joint attention therapies, medications, occupational therapy, physical therapy, social
15 skill training, and speech-language therapy. Treatment for ASD lasts a lifetime, as there is no
16 cure.

17 27. ADHD is a chronic neurodevelopmental disorder resulting in attention difficulty,
18 hyperactivity, and impulsiveness.

19 28. ADHD begins in childhood and persists through adulthood. ADHD contributes
20 to low self-esteem, troubled relationships, and difficulty with school, work, and familial
21 relationships.

22 29. Treatments for ADHD, include, but are not limited to, chronic medication usage
23 and various therapies. Treatment for ADHD lasts a lifetime, as there is no cure.

24 30. In or around 2018, the Center for Disease Control and Prevention (“CDC”)
25 found that 1 in 44 (2.3%) 8-year-old children have been diagnosed with ASD.

26 31. This represents an increase from a prior CDC finding that 1 in 68 U.S. children
27 born in 2002 have ASD, which already represented a more than a 100% increase compared with
28 children born a decade prior.

1 32. As of 2019, 8.8% of children had been diagnosed with ADHD, or roughly
2 325,000 children per year.

3 33. Parental awareness and changes in diagnoses do not fully account for the rapid
4 rise in these diagnoses.

5 34. Rather, neurotoxic exposures, such as prenatal APAP exposure, partly explain a
6 trending increase in diagnoses.

7 35. For decades, beginning in 1987, the scientific community has published studies
8 showing that prenatal ingestion of APAP can cause ASD and ADHD.

9 36. A 2019 meta-analysis of studies from 1987 to 2016, with relative risks ranging
10 from 1.16 to 1.34, found statistically significant nineteen percent (19%) increased risk of ASD
11 in children whose mothers took APAP during pregnancy.

12 37. Since 2013, there have been six European birth cohort studies, examining over
13 70,000 mother-child pairs, showing the association between prenatal use of APAP and ASD and
14 ADHD, confirming the results of studies dating back to 1987.

15 38. The overall body of scientific evidence has shown for decades that prenatal use
16 of APAP can cause ASD and ADHD in the child.

17 39. During all relevant times herein, Defendant was engaged in the business of
18 manufacturing and selling the APAP Products in the United States, and the weight of the
19 scientific evidence available showed prenatal exposure to APAP significantly increases the risk
20 of neurodevelopmental disorders in children exposed to APAP prenatally, including but not
21 limited to ASD and ADHD.

22 40. At the time Plaintiff Mother was pregnant with Plaintiff Child, the scientific
23 evidence regarding the risks of in utero exposure of APAP was available to Defendant, and
24 Defendant knew or should have known that prenatal use of APAP can cause ASD or ADHD.

25 41. Moreover, despite scientific evidence that prenatal use of APAP can cause ASD
26 or ADHD, Defendant continued and continues to market APAP Products as safe pain relievers
27 for pregnant women, making mothers believe they are choosing a safe drug for even minor
28 aches, pains, and headaches.

**Plaintiff Mother Took APAP Products while Pregnant,
and It Caused ASD in Plaintiff Child**

42. Plaintiff Mother used APAP Products while she was pregnant with Plaintiff Child.

43. During her pregnancy with Plaintiff Child, during each trimester, Plaintiff Mother took the APAP Products approximately three to six times a week for pain and discomfort.

44. Plaintiff Mother believed it was safe for her to take APAP Products during her pregnancies.

45. Indeed, Plaintiff Mother was instructed by her health care provider(s) to not take ibuprofen or aspirin while pregnant but was informed she could take APAP freely without risk to Plaintiff Child.

46. There is no warning on the APAP Products' labels specifically addressing the risks of ASD if a mother ingests APAP while pregnant.

47. Had Plaintiff Mother known of the risk of ASD in her child from taking APAP while pregnant, she would not have taken the APAP Products.

48. Plaintiff Child was born on July 1, 2019.

49. Plaintiff Mother started to have concerns about Plaintiff Child's development when Plaintiff Child exhibited developmental delays.

50. Plaintiff Child was diagnosed with autism in September of 2022.

51. Plaintiff Child does not communicate verbally and exhibits repetitive movements/stimming behaviors.

52. Plaintiff Child requires an immense amount of assistance to complete the normal tasks of her daily life.

53. Plaintiff Child's ASD puts an incredible strain on Plaintiff Mother and their family.

54. Plaintiff's Mother fears for Plaintiff Child and experiences substantial stress and anxiety due to the challenges associated with Plaintiff Child's ASD.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

55. Due to Defendant's acts of fraudulent concealment, Defendant is estopped from relying on any statutes of limitations or repose. Such acts include Defendant's intentional concealment from Plaintiff Mother and the general public that APAP is defective when there is prenatal exposure, while continuing to market the APAP Products with the adverse effects described in this Complaint.

56. Given Defendant's affirmative actions of concealment by failing to disclose information about the defects known to it but not the public—information over which Defendant had exclusive control—and because Plaintiff Mother could not reasonably have known that the APAP Products were defective, Defendant is estopped from relying on any statutes of limitations that might otherwise be applicable to the claims asserted in this Complaint.

57. Plaintiffs, in any event, commenced this action within two years of discovering or having reason to discover their causes of action.

CLAIMS FOR RELIEF

COUNT I: STRICT LIABILITY – FAILURE TO WARN

58. Plaintiffs restate, reallege, and incorporate by reference the allegations set forth in the rest of this Complaint as if fully set forth herein.

59. At the time of Plaintiffs' injuries, the APAP Products were defective and unreasonably dangerous to foreseeable consumers using the APAP Products in a foreseeable manner during pregnancy, including Plaintiff Mother, because they lacked an adequate warning.

60. At all relevant times, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, labeling, selling, distributing, and promoting the APAP Products, which were defective and unreasonably dangerous to consumers, including Plaintiff Mother, because they did not contain adequate warnings or instructions concerning the dangerous characteristics of ingesting APAP during pregnancy. These actions were under the ultimate control and supervision of Defendant. At all relevant times, Defendant registered, researched, manufactured, distributed, marketed, labeled, promoted, and sold the APAP

1 Products within this District and aimed the marketing at the ultimate consumer. Defendant was
2 at all relevant times involved in the retail and promotion of the APAP Products marketed and
3 sold in this District.

4 61. Defendant had a duty to warn of the risks associated with the use of the APAP
5 products during pregnancy.

6 62. The APAP Products ingested by Plaintiff Mother during pregnancy were in the
7 same or substantially similar condition as they were when they left possession of the Defendant.

8 63. Defendant expected and intended the APAP Products to reach users such as
9 Plaintiff Mother in the condition in which the APAP Products were sold.

10 64. Plaintiff Mother did not materially alter the APAP Products prior to ingestion.

11 65. Plaintiff Mother ingested the APAP Products during pregnancy as indicated on
12 the APAP Products' labels.

13 66. Plaintiff Mother was unaware of the defects and dangers of the APAP Products
14 during pregnancy and was specifically unaware that prenatal exposure increases the risk of brain
15 and behavioral development of children in utero.

16 67. The labels on the APAP Products to consumers lack any warning specific to
17 pregnant women. The information that Defendant did provide or communicate to consumers
18 failed to contain relevant warnings, hazards, and precautions that would have enabled
19 consumers such as Plaintiff Mother to utilize the products safely and with adequate protection
20 during pregnancy, or to decide to not use or ingest the APAP Products at all.

21 68. This alleged failure to warn is not limited to the information contained on the
22 APAP Products' labeling. Defendant was able, in accord with federal law, to comply with
23 relevant state law by disclosing the known risks associated with exposure to or use of APAP
24 during pregnancy through other non-labeling mediums, including, but not limited to, promotion,
25 advertisements, public service announcements, and/or public information sources. But
26 Defendant did not disclose these known risks through any medium.

27 69. At all relevant times, Defendant had a duty to properly test, develop, design,
28 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, and supply the

1 APAP Products; provide proper warnings for the APAP Products; and take such steps as
2 necessary to ensure the APAP Products did not cause users and consumers, and their children,
3 to suffer from unreasonable and dangerous risks. Defendant had a continuing duty to warn
4 Plaintiff Mother of dangers associated with exposure to or use of APAP during pregnancy.
5 Defendant, as a manufacturer, seller, and/or distributor of pharmaceutical medication, is held to
6 the knowledge of an expert in the field.

7 70. At the time of manufacture, Defendant could have provided the warnings or
8 instructions regarding the full and complete risks of the APAP Products during pregnancy
9 because Defendant knew or should have known of the unreasonable risks of ASD and ADHD
10 associated with prenatal exposure to and/or the use of such products.

11 71. At all relevant times, Defendant failed and deliberately refused to investigate,
12 study, test, or promote the safety of the APAP Products, or to minimize the dangers to
13 consumers of the APAP Products and to those who would foreseeably use or be harmed by the
14 APAP Products, including Plaintiffs.

15 72. Defendant failed to adequately warn consumers, like Plaintiff Mother, about the
16 significant increased risk of neurodevelopmental disorders in children exposed to APAP
17 prenatally, including but not limited to ASD and ADHD.

18 73. Defendant failed to adequately inform reasonably foreseeable consumers, like
19 Plaintiff Mother, of the proper usage of the APAP Products.

20 74. Even though Defendant knew or should have known that APAP posed a grave
21 risk of harm to Plaintiff Child, Defendant failed to exercise reasonable care to warn of the
22 dangerous risks associated with use and prenatal exposure.

23 75. Plaintiff Mother was exposed to the APAP Products during pregnancy without
24 knowledge of their dangerous characteristics.

25 76. At all relevant times, Plaintiff Mother used and/or was exposed to the use of the
26 APAP Products while using them for their intended or reasonably foreseeable purposes during
27 pregnancy, without knowledge of their dangerous characteristics.
28

1 77. Plaintiff Mother could not have reasonably discovered the defects and risks
2 associated with the APAP Products prior to or at the time of Plaintiff consuming APAP during
3 pregnancy. Plaintiff Mother relied upon the skill, superior knowledge, and judgment of
4 Defendant to know about and disclose serious health risks associated with using the APAP
5 Products.

6 78. If Plaintiff Mother had been properly warned of the defects, dangers, and risks
7 associated with prenatal exposure to APAP, Plaintiff Mother would have decided to not ingest
8 the APAP Products at all. Defendant's failure to properly warn of those defects, dangers, and
9 risks associated with prenatal exposure to APAP was a substantial factor in causing Plaintiffs'
10 injuries and damages.

11 79. Defendant is liable to Plaintiffs for injuries caused by Defendant's negligent or
12 willful failure, as described above, to provide adequate warnings or other relevant information
13 and data regarding the appropriate use of the APAP Products and the risks associated with the
14 use of APAP.

15 80. As a direct and proximate result of Defendant placing defective APAP Products
16 into the stream of commerce, and Plaintiff Mother's foreseeable use and ingestion of the APAP
17 Products during pregnancy, Plaintiff Child was exposed to APAP prenatally, causing her to
18 develop ASD.

19 81. As a direct and proximate result of Defendant placing defective APAP Products
20 into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and
21 suffering, emotional distress, lost wages and earning capacity, and diminished quality of life.
22 Plaintiffs respectfully seek all damages to which they may be legally entitled.

23 **COUNT II: NEGLIGENCE**

24 82. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
25 set forth in the rest of this Complaint as if fully set forth herein.

26 83. Although Defendant had a duty to use reasonable care in testing, developing,
27 designing, manufacturing, marketing, labeling, selling, distributing, promoting, and preparing
28 written instructions and warnings for the APAP Products, Defendant failed to do so.

1 84. Defendant, directly or indirectly, caused the APAP Products to be sold,
2 distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff Mother. At all
3 relevant times, Defendant registered, researched, manufactured, distributed, marketed,
4 promoted, and sold the APAP Products within this district and aimed at a consumer market
5 within this district.

6 85. Defendant knew, or in the exercise of reasonable care should have known, that
7 the APAP Products were defectively and unreasonably designed and/or manufactured, and/or
8 marketed, and were unreasonably dangerous and likely to injure persons that were prenatally
9 exposed to them. Defendant knew or should have known that Plaintiff Mother was unaware of
10 the dangers and defects inherent in the APAP Products when she was ingesting them during her
11 pregnancy with Plaintiff Child.

12 86. At all relevant times, Defendant had a duty to exercise reasonable care in the
13 marketing, advertisement, promotion, and sale of the APAP Products. Defendant's duty of care
14 owed to consumers and the general public included providing accurate, true, and correct
15 information concerning the risks of using APAP during pregnancy and appropriate, complete,
16 and accurate warnings concerning the potential adverse effects of APAP and, in particular, the
17 significantly increased risk of causing neurodevelopmental disorders in children through
18 prenatal exposure to APAP.

19 87. At all relevant times, Defendant knew or, in the exercise of reasonable care,
20 should have known of the hazards and dangers of APAP ingestion while pregnant and,
21 specifically, the significantly increased risk of causing neurodevelopmental disorders in
22 children through prenatal exposure to APAP.

23 88. Defendant failed to provide any kind of warning to pregnant consumers, like
24 Plaintiff Mother, about the significantly increased risk of causing neurodevelopmental disorders
25 in children through prenatal exposure to APAP.

26 89. Accordingly, at all relevant times, Defendant knew or, in the exercise of
27 reasonable care, should have known that use of the APAP Products during pregnancy could
28 cause Plaintiffs' injuries, and thus, create a dangerous and unreasonable risk of injury to the

1 users of these products, including Plaintiffs.

2 90. As such, Defendant breached its duty of reasonable care and failed to exercise
3 ordinary care in the design, research, development, manufacture, testing, marketing, labeling,
4 supply, promotion, advertisement, packaging, sale, and distribution of the APAP Products, in
5 that Defendant manufactured and produced defective APAP Products, which carry the
6 significantly increased risk of causing neurodevelopmental disorders in children through
7 prenatal exposure to APAP; knew or had reason to know of the defects inherent in the APAP
8 Products; knew or had reason to know that a user's or consumer's use of the APAP Products
9 during pregnancy created a significant risk of harm and unreasonably dangerous side effects;
10 and failed to prevent or adequately warn of these risks and injuries.

11 91. Defendant had a duty to disclose the truth about the risks associated with
12 exposure to or use of APAP during pregnancy in its promotional efforts outside of the context
13 of labeling. Defendant was negligent in its promotion of APAP outside of the labeling context
14 by failing to disclose material risk information as part of its promotion and marketing of the
15 APAP Products, including through the internet, television, and print advertisements.

16 92. Despite Defendant's ability and means to investigate, study, and test the APAP
17 Products and to provide adequate warnings regarding use during pregnancy, Defendant failed to
18 do so. Indeed, Defendant wrongfully concealed information and further made false and/or
19 misleading statements concerning the safety and use of APAP.

20 93. Defendant's negligence included:

21 a. Manufacturing, producing, promoting, formulating, creating, developing,
22 designing, selling, and/or distributing the APAP Products while negligently
23 and/or intentionally concealing and failing to disclose the results of trials,
24 tests, and studies of APAP and the significantly increased risk of causing
25 neurodevelopmental disorders in children through prenatal exposure to
26 APAP, and, consequently, the risk of serious harm associated with human
27 use of APAP during pregnancy;

28 b. Failing to undertake sufficient studies and conduct necessary tests to

1 determine whether or not the APAP Products were safe for its intended
2 consumer use and unborn children;

3 c. Failing to provide adequate instructions, guidelines, and safety precautions to
4 those persons Defendant could reasonably foresee would use the APAP
5 Products during pregnancy;

6 d. Failing to disclose to Plaintiff Mother, users, consumers, and the general
7 public that use of APAP during pregnancy presents severe risks of
8 neurodevelopmental disorders in children exposed to APAP prenatally; and

9 e. Failing to warn Plaintiff Mother, users, consumers, and the general public
10 that the APAP Products' risk of harm was unreasonable and that there were
11 safer and effective alternative medications or treatments available to Plaintiff
12 Mother and other users and/or consumers;

13 f. Representing that the APAP Products were safe for their intended purposes
14 for pregnant women when, in fact, Defendant knew or should have known
15 the APAP Products were not safe for their intended purposes; and

16 g. Declining to make or propose any changes to the APAP Products' labeling or
17 other promotional materials that would alert users, consumers, and the
18 general public of the risks of APAP, including to pregnant women;

19 h. Advertising, marketing, and recommending the use of the APAP Products
20 during pregnancy, while concealing and failing to disclose or warn of the
21 dangers known by Defendant to be caused by the use of or exposure to
22 APAP;

23 i. Continuing to disseminate information to its consumers and the general
24 public, which indicates or implies that the APAP Products are not unsafe for
25 pregnant consumer use; and

26 j. Continuing the manufacture and sale of the APAP Products with the
27 knowledge that the APAP Products were unreasonably unsafe and dangerous.
28

1 94. Defendant knew and/or should have known that it was foreseeable that children
2 such as Plaintiff Child would suffer injuries as a result of Defendant's failure to exercise
3 ordinary care in the manufacturing, marketing, labeling, distribution, and sale of the APAP
4 Products to pregnant consumers, like Plaintiff Mother.

5 95. Plaintiff Mother did not know the nature and extent of the injuries that could
6 result in her child from the intended use of and/or exposure to APAP prenatally.

7 96. Defendant's negligence was a proximate cause of Plaintiffs' injuries, i.e., absent
8 Defendant's negligence, Plaintiff Child would not have developed ASD. That negligence was a
9 substantial factor in causing Plaintiffs' injuries and damages.

10 97. Defendant's conduct, as described above, was reckless. Defendant regularly
11 risked exposing Plaintiff Mother to the APAP Products while pregnant with Plaintiff Child, with
12 full knowledge of the dangers of the APAP Products and that it could cause ASD in Plaintiff
13 Child. Defendant made conscious decisions not to redesign, re-label, warn, or inform the
14 unsuspecting public, including Plaintiff Mother. Defendant's reckless conduct therefore
15 warrants an award of punitive damages.

16 98. As a direct and proximate result of Defendant placing the defective APAP
17 Products into the stream of commerce, Plaintiffs have suffered permanent injuries, significant
18 pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality
19 of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

20 **COUNT III: BREACH OF EXPRESS WARRANTY**

21 99. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
22 set forth in the rest of this Complaint as if fully set forth herein.

23 100. At all material times, Defendant manufactured, marketed, sold, distributed, and
24 otherwise placed into the stream of commerce the APAP Products. These actions were under
25 the ultimate control and supervision of Defendant.

26 101. In advertising, marketing, and promoting the APAP Products to consumers, like
27 Plaintiff Mother, Defendant expressly warranted that the APAP Products were safe for use and
28 reasonably fit for their intended purposes, including use by pregnant mothers. In advertising,

1 marketing, and otherwise promoting the APAP Products, Defendant intended for pregnant
2 consumers to rely upon its representations regarding safety and fitness, in an effort to induce
3 them to purchase and consume the APAP Products during pregnancy to relieve pain.

4 102. Defendant expressly warranted to Plaintiff Mother and pregnant consumers that
5 the APAP Products were safe for ingestion during pregnancy.

6 103. Defendant had a duty to exercise reasonable care in the research, development,
7 design, testing, packaging, manufacture, inspection, labeling, distributing, marketing,
8 promotion, sale, and release of the APAP Products, including a duty to:

- 9 a. ensure that the APAP Products during pregnancy did not cause users and
10 their unborn children unreasonably dangerous side effects; and
11 b. warn of dangerous and potentially incurable side effects; and
12 c. disclose adverse material facts, such as the true risks associated with the use
13 of and exposure to APAP during pregnancy, when making representations to
14 users, consumers, and the general public, including Plaintiff Mother.

15 104. Defendant had the ability to properly disclose the risks associated with APAP
16 usage during pregnancy through multiple channels, not just labeling.

17 105. At all relevant times, Defendant expressly represented and warranted to the
18 purchasers of the APAP Products, by and through statements made by Defendant in labels,
19 publications, brochures, and other written materials intended for consumers and the general
20 public, that the APAP Products were safe to human health and the environment, effective, fit,
21 and proper for their intended use during pregnancy. Defendant advertised, labeled, marketed,
22 and promoted the APAP Products, representing the quality to consumers and the public in such
23 a way as to induce their purchases or use during pregnancy, thereby making an express warranty
24 that the APAP Products would conform to the representations.

25 106. The representations about the APAP Products, as set forth herein, contained, or
26 constituted affirmations of fact or promises made by the seller to the buyer, which related to the
27 goods and became part of the basis of the bargain, creating an express warranty that the goods
28 would conform to the representations.

1 107. Defendant breached express representations and warranties made to Plaintiff
2 Mother, with respect to the APAP Products, including the following:

- 3 a. Defendant represented through their labeling, advertising, and marketing
4 materials that the APAP Products were safe for use during pregnancy, and
5 intentionally withheld and concealed information about the risks of serious
6 injury associated with use of APAP and by expressly limiting the risks
7 associated with use during pregnancy within its warnings and labels; and
8 b. Defendant represented that the APAP Products were safe for use and
9 intentionally concealed information that demonstrated that APAP carries the
10 significantly increased risk of causing neurodevelopmental disorders in
11 children through prenatal exposure to APAP, and that the APAP Products,
12 therefore, were not safer than alternatives available on the market.

13 108. Plaintiff Mother detrimentally relied on the express warranties and
14 representations of Defendant concerning the safety and/or risk profile of APAP during
15 pregnancy in deciding to purchase the APAP Products. Plaintiff Mother reasonably relied upon
16 Defendant to disclose known defects, risks, dangers, and side effects of APAP. Plaintiff Mother
17 would not have purchased or used the APAP Products during pregnancy had Defendant
18 properly disclosed the risks associated with the APAP Products, either through advertising,
19 labeling, or any other form of disclosure. Defendant's breach of the express warranties and
20 representations concerning the safety and/or risk profile of APAP during pregnancy was a
21 substantial factor in causing Plaintiffs' injuries and damages.

22 109. Plaintiff Mother had no knowledge of the falsity or incompleteness of
23 Defendant's statements and representations concerning the APAP Products and could not have
24 taken reasonable steps to notify Defendant of those matters or to seek repair or other remedies.

25 110. Plaintiff Mother used and/or was exposed to APAP during pregnancy as
26 researched, developed, designed, tested, manufactured, inspected, labeled, distributed,
27 packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by
28 Defendant.

111. Had the warnings, labels, advertisements, or promotional material for the APAP Products accurately and adequately set forth the true risks associated with the use of such Products during pregnancy, including Plaintiffs' injuries, rather than expressly excluding such information, and warranting that the APAP Products were safe for their intended use, Plaintiffs could have avoided the injuries complained of herein.

112. As a direct and proximate result of Defendant's breach of express warranty, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT IV: BREACH OF IMPLIED WARRANTY

113. Plaintiffs restate, reallege, and incorporate by reference each of the allegations set forth in the rest of this Complaint as if fully set forth herein.

114. At all material times, Defendant manufactured, marketed, sold, distributed, and otherwise placed the APAP Products into the stream of commerce.

115. At all material times, Defendant intended for the APAP Products to be consumed and ingested by pregnant women, like Plaintiff Mother; and Defendant impliedly warranted that the APAP Products and their component parts were of merchantable quality, safe, fit for such use, and adequately tested.

116. Defendant was aware that consumers, including Plaintiff Mother, would consume and ingest the APAP Products as directed by the Products' labels and promotional materials. Therefore, Plaintiff Mother was a foreseeable user of the APAP Products.

117. But Defendants failed to disclose that APAP has dangerous propensities when used as intended during pregnancy and that use of the APAP Products carries an increased risk of developing severe injuries, including Plaintiff Child's injuries.

118. The APAP Products were expected to reach, and did in fact reach consumers, including Plaintiff Mother, without substantial change in the condition in which they were manufactured and sold by Defendant.

119. Plaintiff Mother was an intended beneficiary of the implied warranties made by

1 Defendant to purchasers of the APAP Products, including Plaintiff Mother.

2 120. In reliance upon Defendant's implied warranties, Plaintiff Mother purchased and
3 used the APAP Products as indicated, and in the foreseeable manner normally intended,
4 recommended, promoted, and marketed by Defendant. The failure of the APAP Products to be
5 of merchantable quality, to be safe or fit for their intended use, or to be adequately tested was a
6 substantial factor in causing Plaintiffs' injuries and damages.

7 121. Defendant breached its implied warranties to Plaintiffs in that the APAP
8 Products were not of merchantable quality, nor were they safe or fit for their intended use or
9 adequately tested.

10 122. The harm caused by the APAP Products far outweighed their benefit, rendering
11 the APAP Products more dangerous than an ordinary consumer or user would expect and more
12 dangerous than alternative products.

13 123. As a direct and proximate result of Defendant's breach of implied warranties,
14 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress,
15 lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all
16 damages to which they may be legally entitled.

17 **COUNT V: VIOLATION OF CONSUMER PROTECTION LAWS**

18 124. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
19 set forth in the rest of this Complaint as if fully set forth herein.

20 125. Plaintiff Mother purchased and used the APAP Products for primarily personal
21 use and pain relief during pregnancy, thereby suffering ascertainable losses as a result of
22 Defendant's actions in violation of the consumer protection laws.

23 126. Had Defendant not engaged in the deceptive conduct described in this
24 Complaint, Plaintiff Mother would not have purchased and/or paid for the APAP Products, and
25 Plaintiffs would not have incurred related injury medical costs.

26 127. Defendant engaged in wrongful and unlawful conduct, while at the same time,
27 obtaining under false pretenses moneys from Plaintiff Mother for the APAP Products. Those
28 moneys would not have been paid had Defendant not engaged in unfair and deceptive conduct.

1 Plaintiffs actually relied upon Defendant's misrepresentations and deception concerning the
2 APAP Products.

3 128. Defendant engaged in the following unfair methods of competition or deceptive
4 acts or practices, which are proscribed by law:

- 5 A. representing that goods or services have characteristics,
6 ingredients, uses, benefits, or qualities they do not have;
- 7 B. advertising goods or services with the intent not to sell them as
8 advertised; and
- 9 C. engaging in fraudulent or deceptive conduct creating a likelihood
10 of confusion or misunderstanding.

11 129. Plaintiffs were injured by the cumulative nature of Defendant's conduct. The
12 cumulative effect, directed at patients, physicians, and consumers, was to create demand for and
13 sell the APAP Products. Each aspect of Defendant's conduct combined to artificially create
14 sales of the APAP Products, including to Plaintiff Mother who did, in fact, purchase the APAP
15 Products.

16 130. Defendant had a statutory duty to refrain from unfair or deceptive acts or trade
17 practices in the design, labeling, development, manufacture, promotion, and sale of the APAP
18 Products.

19 131. Defendant's deceptive, unconscionable, or fraudulent representations and
20 material omissions to consumers, including Plaintiff Mother, constitute unfair and deceptive
21 acts and trade practices in violation of the federal and state consumer protection statutes listed
22 below.

23 132. Defendant's actions, as complained of in this Complaint, constitute unfair
24 competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in
25 violation of the federal and state consumer protection statutes listed below.

26 133. Defendant has engaged in unfair competition, or unfair or deceptive acts or trade
27 practices, or has made false representations under the following statutes:

- 28 • 15 U.S.C. §§ 2301–12 (1982);

- Cal. Bus. & Prof. Code § 17200, et seq.;
- Cal. Civ. Code § 1750 et seq.

134. To protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising, Defendant, as the supplier, manufacturer, advertiser, and seller, is subject to liability under the above legislation enacted against unfair, deceptive, fraudulent, and unconscionable consumer sales practices. The California Unfair Competition Law (“UCL”) prohibits “any unlawful, unfair, or fraudulent business act or practice and unfair, deceptive, untrue, or misleading advertising and any act prohibited by” Section 17500 of the California Business and Professions Code. Section 17500, in turn, prohibits any untrue or misleading statements made in connection with the sale of goods. The Consumers Legal Remedies Act (“CLRA”) defines as statutorily unlawful certain unfair methods of competition and unfair or deceptive practices. Cal. Civ. Code § 1750 et seq.

135. By knowingly and falsely representing that the APAP Products were fit to be used for the purposes for which they were intended—when in fact they were defective and dangerous when used during pregnancy—and by other acts alleged, Defendant violated the above statutes, enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising.

136. Defendant’s actions and omissions are uncured or incurable deceptive acts under the above legislation.

137. Defendant had actual knowledge of the defective and dangerous conditions of the APAP products but failed to take any action to cure such defective and dangerous conditions.

138. Plaintiff Mother relied upon Defendant’s misrepresentations and omissions in determining which APAP Products (if any) to ingest.

139. Defendant’s deceptive, unconscionable, or fraudulent representations and material omissions to consumers constituted unfair and deceptive acts and practices.

140. By reason of the unlawful acts in which Defendant engaged, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

1 141. As a direct and proximate result of Defendant's violations of the above-listed
2 legislation, Plaintiffs have sustained economic losses and other damages and are entitled to
3 statutory and compensatory damages, including restitution, in an amount to be proven at trial
4 and civil penalties as permitted by law.

5 **COUNT VI: NEGLIGENT MISREPRESENTATION**

6 142. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
7 set forth in the rest of this Complaint as if fully set forth herein.

8 143. Defendant had a duty to accurately and truthfully represent to consumers,
9 including to Plaintiff Mother and to the public, that the APAP Products had not been adequately
10 tested and found to be a safe and effective treatment for pregnant women. Defendant breached
11 that duty as its representations of the safety of the APAP Products were false. Defendant
12 intended for consumers like Plaintiff Mother to rely upon that representation, and Plaintiff
13 Mother did justifiably rely on Defendant's misrepresentations concerning the APAP Products'
14 high risk of unreasonable and dangerous adverse side effects when ingested or used during
15 pregnancy.

16 144. Defendant failed to exercise ordinary care in the representations concerning the
17 APAP Products while Defendant was involved in the manufacture, sale, testing, quality
18 assurance, quality control, and distribution in interstate commerce, because Defendant
19 negligently misrepresented the APAP Products' high risk of unreasonable and dangerous
20 adverse side effects when ingested or used during pregnancy.

21 145. Defendant also breached its duty in representing to Plaintiff Mother that the
22 APAP Products had no serious side effects when ingested during pregnancy. Defendant
23 intended for consumers like Plaintiff Mother to rely upon that representation, and Plaintiff
24 Mother did justifiably rely upon that representation.

25 146. Defendant knew or had reason to know that the APAP Products had been
26 insufficiently tested or had not been tested at all, and that they lacked adequate and accurate
27 warnings, and created a high risk, or a higher than acceptable reported and represented risk, of
28 adverse side effects. Those side effects include neurodevelopmental disorders in children, such

1 as ASD and ADHD. Thus, Defendant lacked reasonable ground for believing the
2 representations to be true and intended for consumers like Plaintiff Mother to rely upon those
3 misrepresentations by purchasing the APAP products for use during pregnancy. Plaintiff Mother
4 justifiably relied upon those misrepresentations in purchasing and using the APAP products
5 while pregnant. Defendant's negligent misrepresentation concerning the safety and/or risk
6 profile of using APAP during pregnancy was a substantial factor in causing Plaintiffs' injuries
7 and damages.

8 147. As a direct and proximate result of Defendant's negligent misrepresentation,
9 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress,
10 lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all
11 damages to which they may be legally entitled.

12 **PUNITIVE DAMAGES**

13 148. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
14 set forth in the rest of this Complaint as if fully set forth herein.

15 149. Defendant has acted with malice through despicable conduct that exhibits a
16 willful and conscious disregard for the rights and safety of others, including Plaintiffs, and has
17 acted with oppression in subjecting Plaintiffs to cruel and unjust hardship in conscious disregard
18 of their rights. Further, Defendant has intentionally misrepresented or concealed material facts
19 known to it with the intention of causing injury or otherwise depriving Plaintiffs of their
20 property or legal rights.

21 150. Defendant failed to adequately test and study the APAP Products to determine
22 and ensure that the APAP Products were safe and effective for use during pregnancy before
23 releasing them for sale for human consumption.

24 151. Further, Defendant continued to manufacture and sell the APAP Products and
25 marketed them for use during pregnancy, even after obtaining knowledge and information that
26 the APAP Products were defective and unreasonably unsafe because they, among other things,
27 did not include adequate warnings.

28 152. Defendant was aware of the probable consequences of the dangerous and

1 defective product, including the risk of neurodevelopmental disorders in children, such as ASD
2 and ADHD, when they suffered prenatal exposure.

3 153. At all material times, Defendant knew or should have known that the APAP
4 Products were inherently dangerous with respect to the following: the risk of
5 neurodevelopmental disorders in children, such as ASD and ADHD, when they suffered
6 prenatal exposure; pain and suffering; loss of life's enjoyment; and unsuccessful treatments to
7 cure the conditions proximately related to the use of the APAP Products, as well as the other
8 permanent and lasting severe personal injuries.

9 154. Defendant knowingly withheld material information from consumers and the
10 public, including Plaintiff Mother, concerning the safety and efficacy of the APAP Products
11 during pregnancy, which deprived Plaintiff Mother of vitally necessary information with which
12 to make a fully informed decision about whether to use the APAP Products while pregnant.

13 155. At all material times, Defendant also knew and recklessly and/or intentionally
14 disregarded the fact that the APAP Products, when used during pregnancy, can cause
15 debilitating and life-altering side effects with greater frequency than safer alternative methods,
16 products, and/or treatments. But Defendants recklessly failed to advise the medical community
17 and the general public, including Plaintiff Mother, of that fact.

18 156. At all material times, Defendant intentionally misstated and misrepresented data;
19 and Defendant continues to misrepresent data so as to minimize the perceived risk of injuries
20 and the rate of complications caused by or associated with the APAP Products.

21 157. Notwithstanding the foregoing and the growing body of knowledge and
22 information regarding the true and defective nature of the APAP Products, with their increased
23 risk of side effects and serious complications, Defendant continues to aggressively market the
24 APAP Products to consumers, including the pregnant community at large, without disclosing
25 the true risk of the complications and side effects.

26 158. When Plaintiff Mother consumed the APAP Products and since then, Defendant
27 has known the APAP Products were defective and unreasonably dangerous without an adequate
28 warning. But Defendant continued to manufacture, produce, assemble, market, distribute, and

1 sell the APAP Products to the pregnant community so as to maximize sales and profits at the
 2 expense of the health and safety of expecting mothers in a conscious, reckless, and/or
 3 intentional disregard of the likely and foreseeable harm caused by the APAP Products to
 4 members of the public, including Plaintiffs.

5 159. At all material times, Defendant has concealed and/or failed to disclose to the
 6 public the serious risks and the potential complications associated with the APAP Products, so
 7 as to ensure continued and increased sales and profits and to the detriment of the public,
 8 including Plaintiffs.

9 160. Defendant's acts and omissions are of such character and nature so as to entitle
 10 Plaintiffs to an award of punitive damages in accordance with applicable statutory and common
 11 law. Defendant's conduct shows malice, oppression, or fraud, or that entire want of care, raising
 12 the presumption of conscious indifference to consequences of that conduct, thereby justifying
 13 an award of punitive damages.

14 WHEREFORE, Plaintiffs demand judgment against Defendant individually, and jointly
 15 and severally. Plaintiffs also request compensatory damages, punitive damages, or enhanced
 16 compensatory damages, together with interest, costs of suit, attorneys' fees, and such further
 17 relief as the Court deems equitable and just.

18 **PRAYER FOR RELIEF**

19 Plaintiffs demand judgment against Defendant individually, and jointly and severally,
 20 and pray for the following relief in accordance with applicable law and equity:

- 21 i. Compensatory damages to Plaintiffs for past, present, and future
 22 damages, including pain and suffering for severe and permanent personal
 23 injuries sustained by Plaintiffs, permanent impairment, mental pain and
 24 suffering, loss of enjoyment of life, health and medical care costs,
 25 economic damages, together with interest and costs as provided by law;
- 26 ii. Restitution and disgorgement of Defendant's profits;
- 27 iii. Punitive or enhanced compensatory damages;
- 28 iv. Reasonable attorneys' fees as provided by law;

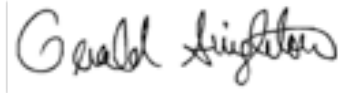
- 1 v. Past and future costs of all proceedings;
2 vi. All ascertainable economic damages;
3 vii. Prejudgment interest on all damages as allowed by law; and
4 viii. Such other and further relief as this Court deems just and proper.

5 **DEMAND FOR JURY TRIAL**

6 Plaintiffs hereby demand a trial by jury on all issues so triable.

7 Dated: September 29, 2022

Respectfully submitted,

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9 Gerald Singleton
10 California State Bar No. 208783
11 gsingleton@singletonschreiber.com
12 Singleton Schreiber, LLP
13 2945 Townsgate Rd.
Westlake Village, Suite 200
Thousand Oaks, CA 91361
Direct: (805) 256-1116

14 Mikal C. Watts (Pro Hac Forthcoming)
15 Texas State Bar No. 20981820
16 mcwatts@wattsguerra.com
17 Alicia D. O'Neill (Pro Hac Forthcoming)
18 Texas State Bar No. 24040801
19 aoneill@wattsguerra.com
Watts Guerra LLC
5726 W. Hausman Dr., Suite 119
San Antonio, Texas 78249
Direct: (210) 447-0500

20 *ATTORNEYS FOR PLAINTIFFS*
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